

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 08-13(DSD/JJG)

American Insurance Company,

Plaintiff,

v.

ORDER

St. Jude Medical, Inc.,

Defendant.

Bethany K. Culp, Esq., Michelle D. Mitchell, Esq.,
Paulette S. Sarp, Esq., and Hinshaw & Culbertson, 333
South Seventh Street, Minneapolis, MN 55402, counsel for
plaintiff.

Jonathan M. Bye, Esq., Thomas C. Mielenhausen, Esq.,
Christopher L. Lynch, Esq., Meghan M. Elliott, Esq. and
Lindquist & Vennum, 4200 IDS Center, 80 South Eighth
Street, Minneapolis, MN 55402, counsel for defendant.

This matter is before the court upon a motion for partial
summary judgment by defendant St. Jude Medical, Inc. (St. Jude).
Based on a review of the file, record and proceedings herein, and
for the following reasons, the court grants St. Jude's motion.

BACKGROUND

In this insurance-coverage dispute, plaintiff American
Insurance Company (AIC)¹ seeks a declaration that it has no duty to

¹ AIC is a Nebraska corporation with its principal place of
business in California.

defend or indemnify St. Jude² for claims arising from St. Jude's Silzone-coated³ artificial heart valves. The dispute involves an eight-layer, \$250 million products-liability insurance program, which covers St. Jude's products on a claims-made basis between January 31, 1999, and January 31, 2000 (Policy Period). AIC provided the sixth layer of excess insurance consisting of \$50 million in excess of \$150 million, and followed form to the primary insurer (AIC Policy).

Medmarc Casualty Insurance Company (Medmarc) provided the primary insurance for bodily injury due to a "products/completed operations hazard" (Medmarc Policy). See Ladner Aff. Ex. 1, at 300. Section I(1)(b) of the Medmarc Policy states:

This insurance applies to "bodily injury" ... only if:
(1) The "bodily injury" ... is caused by an "occurrence" ...
(2) The "bodily injury" ... did not occur ... after the end of the policy period; and
(3) A claim for damages because of the "bodily injury" ... is first made against any insured [and notice of such claim is received and recorded by St. Jude or Medmarc] ... during the policy period.

Id. The Medmarc Policy further states that the date of occurrence is the earlier of the date on which, "a claim is made or 'suit' is

² St. Jude is a Minnesota corporation with its principal place of business in Minnesota.

³ Silzone is a coating of elemental silver that St. Jude began using on some artificial heart valves in 1998.

brought alleging injury or damage resulting from your product ... [or] the date of the 'advisory memorandum' initiated by [St. Jude]." Id. at 309. An advisory memorandum is defined as "any communication issued by [St. Jude] to inform health professionals or other appropriate persons or firms of a risk of substantial harm from a product in commercial use." Id. The Medmarc Policy includes an endorsement entitled "Batch Clause," which amends the definition of occurrence:

The term "batch" means all products which have the same known or suspected defect or deficiency which is identified by the same advisory memorandum.

The term "advisory memorandum" is any communication issued by you to inform health professionals or other appropriate persons or firms of a risk of "bodily injury" ... from a product in use.

...

When this endorsement is attached to your policy, all losses arising from a single "batch" of your product will be considered to be one "occurrence." Therefore, when multiple losses are considered to be one "occurrence" you must only meet a single "self insured retention" amount. Likewise, our limit of liability due to "bodily injury" ... is limited to that of a single "occurrence[.]"

All claims made by persons or organizations seeking damages because of "bodily injury" ... will be deemed to have been made at the time of the first of those claims is made against you.

Id. at 323.

The excess insurers each follow form to the Medmarc Policy. See id. Ex. 2, at 361 (St. Paul Fire and Marine Insurance Company); id. Ex. 3, at 370 (American International Speciality Lines Insurance Company); id. Ex. 4, at 382 (TIG Speciality Insurance Company); id. Ex. 5, at 400 (Gulf Insurance Company); id. Ex. 6, at 424 (Lumbermens Mutual Casualty Company); id. Ex. 7, at 444 (Chubb Custom Insurance Company); id. Ex. 8, at 475 (Northfield Insurance Company); id. Ex. 9, at 501 (TIG Specialty Insurance Company); id. Ex. 10, at 518 (AIC); id. Ex. 11, at 532 (Lumbermens Mutual Casualty Company); id. Ex. 12, at 558 (TIG Specialty Insurance Company); id. Ex. 13, at 571 (American International Speciality Lines Insurance Company, following form to St. Paul Fire and Marine Insurance Company policy).

The AIC Policy states that it applies "[t]he definitions, terms, conditions, limitations, exclusions, and warranties of the [Medmarc] policy ... unless they are inconsistent with provisions of this policy, or relate to premium, subrogation, an obligation to investigate and defend, the amount or limits of insurance, payment of expenses, cancellation or any renewal agreement." Id. Ex. 10, at 518. The AIC Policy covers claims first made against St. Jude "during [AIC's] policy period" when "the injury or damage takes place on or after [December 18, 1987] ... and prior to the

termination of this policy," id. at 518, 525, and applies "only after all Underlying Insurance has been exhausted by payment of their limits of insurance," id. at 522.

St. Jude's Silzone-coated products were the subject of the Artificial Valve Endocarditis Reduction Trial (AVERT). On January 21, 2000, the AVERT review board recommended discontinuing enrollment in the trial, because the data indicated a significantly higher incidence of explants due to paravalvular leakage among the Silzone study group than the non-Silzone group. That same day, St. Jude sent a letter to physicians entitled "**URGENT - MEDICAL DEVICE RECALL & ADVISORY**" that announced a recall of its Silzone-coated products. Id. Ex. 27. The letter stated that "St. Jude Medical has received information that indicates that there is a statistically significant higher rate of paravalvular leak leading to valve explants in patients implanted with St. Jude Medical mechanical heart valves with Silzone coated sewing cuffs." Id. The same day, St. Jude sent a separate letter further explaining its reasons for recalling the Silzone-coated products. In the second letter, St. Jude stated that, "[b]ased on our internal investigation, we have concluded that the explants due to paravalvular leak in the AVERT study are not related to the

manufacturing of the valve or the manufacturing of the Silzone coated sewing cuff.”⁴ Id. Ex. 28.

On January 24, 2000, St. Jude notified its insurers of the January 21, 2000, advisory. Id. Ex. 29. On January 28, 2000, St. Jude notified Medmarc of claims related to its Silzone-coated products. Id. Ex. 31. Thereafter, Medmarc determined that “it appears that claims by patients who have been diagnosed with paravalvular leak and/or any other complication allegedly caused by a Silzone coated product would constitute claims for damages because of ‘bodily injury’ that would trigger coverage.” Id. Ex. 37, at 21599. Medmarc also determined that “it appears that all claims arising out of the Silzone recall will constitute a single ‘occurrence’ ... [and] all claims arising from products that are the subject of the recall will be deemed to have been made during the [1999 to 2000] Policy Period.” Id. Medmarc then paid defense and settlement costs until its \$10 million limit was exhausted. The excess insurers at each successive layer followed form as their layers were reached.

AIC monitored the Silzone litigation until March 2002, when it determined that “it now seems very unlikely that our policy will be

⁴ At oral argument and in its briefing, AIC argued that St. Jude’s decision to recall its Silzone-coated products (and thereby to expose itself and its insurers to lawsuits) was in fact a way to take products with underperforming sales off the market. See, e.g., Pl.’s Resp. Mem., 6-11, June 4, 2010. The court determines that consideration of AIC’s argument is unnecessary to the disposition of this motion.

exposed.” Id. Ex. 56. AIC then requested to be removed from future litigation updates unless the claims approached \$100 million. Id. AIC stated, “[a]lthough our policy does not appear to us to be at risk, we must point out that our policy follows form with those beneath us. For that reason, we reserve all rights to raise coverage issues also raised by those underlying carriers.” Id. On November 2, 2006, AIC sent a letter to St. Jude about the Silzone claims, stating that it had a right, but not a duty, to defend St. Jude. See Jones Aff. Ex. 57, at 50-51. AIC further stated that it would only pay defense costs if it exercised its right to defend. Id. Lastly, AIC stated that “the batch clause does not eliminate the requirement found in the AIC policy that the ‘bodily injury’ must occur ... [before January 31, 2000].” Id. at 55.

AIC filed this action on January 2, 2008, seeking declarations that it has no duty to defend or reimburse St. Jude for its defense of the Silzone litigation, to pay for claims not made to St. Jude during the policy period, to pay for relief to the class in In re St. Jude Medical Inc. Silzone Heart Valves Products Liability Litigation (In re Silzone), or to pay St. Jude for costs of the AVERT. See Compl. ¶¶ 14-15. On February 20, 2008, St. Jude counterclaimed, claiming breach of contract and seeking declarations that AIC is obligated to pay the defense costs, fees and expenses for claims that fall within its layer, including those

for the AVERT; that the Batch Clause places all claims and bodily injuries arising from a Silzone-coated product subject to the January 2000 recall into the Policy Period; and that AIC has a duty to indemnify St. Jude for settlements or judgments in In re Silzone. See Countercl. ¶¶ 68-76.

On November 10, 2009, St. Jude moved for partial summary judgment on its request for a declaration that the Batch Clause places all claims and bodily injuries arising from Silzone-coated products into the Policy Period and that AIC is obligated to indemnify St. Jude for the Silzone claims that arose in AIC's layer. Following several postponements due to discovery disputes, the court heard argument on the instant motion on June 25, 2010. The court now considers the motion.

DISCUSSION

Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56©; see *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A fact is material only when its resolution affects the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute is genuine if the evidence is such that it could

cause a reasonable jury to return a verdict for either party. See *id.* at 252.

On a motion for summary judgment, the court views all evidence and inferences in a light most favorable to the nonmoving party. See *id.* at 255. The nonmoving party, however, may not rest upon mere denials or allegations in the pleadings but must set forth specific facts sufficient to raise a genuine issue for trial. See *Celotex*, 477 U.S. at 324. Moreover, if a plaintiff cannot support each essential element of his claim, the court must grant summary judgment because a complete failure of proof regarding an essential element necessarily renders all other facts immaterial. *Id.* at 322-23.

The court applies Minnesota law in this diversity case. See *Source Food Tech., Inc. v. U.S. Fid. & Guar. Co.*, 465 F.3d 834, 836 (8th Cir. 2006). In Minnesota, an insurer's liability is governed by the terms of the insurance policy. See *Thommes v. Milwaukee Ins. Co.*, 641 N.W.2d 877, 882 (Minn. 2002) (citation omitted). Interpretations of an insurance policy and an insurer's duty to defend and indemnify are questions of law. *Id.* at 879. The court interprets an insurance policy in accordance with general principles of contract construction, reading unambiguous language according to its plain and ordinary meaning and giving effect to the intent of the parties. *Id.*; see also *Travelers Indem. Co. v. Bloomington Steel & Supply Co.*, 718 N.W.2d 888, 894 (Minn. 2006).

It is well established that doubts about the meaning of language of an insurance policy must be resolved in favor of the insured. See *Columbia Heights Motors, Inc. v. Allstate Ins. Co.*, 275 N.W.2d 32, 36 (Minn. 1979).

The insured has the burden to establish a prima facie case of coverage. *SCSC Corp. v. Allied Mut. Ins. Co.*, 536 N.W.2d 305, 311 (Minn. 1995), overruled on other grounds by *Bahr v. Boise Cascade Corp.*, 766 N.W.2d 910, 919 (Minn. 2009). If coverage is established, the burden shifts to the insurer to prove that a policy exclusion applies. *Id.* at 313. Provisions limiting liability are construed against the insurer. See *Thommes*, 641 N.W.2d at 880; see also *Westchester Fire Ins. v. Wallerich*, 563 F.3d 707, 712 (8th Cir. 2009) (citation omitted). Once the insurer demonstrates that an exclusion applies, the insured bears the burden of proving an exception to the exclusion. *SCSC Corp.*, 536 N.W.2d at 314.

I. The Batch Clause

St. Jude first argues that all claims arising out of Silzone-coated products are aggregated into the Policy Period.⁵ AIC responds that the Batch Clause does not alter the requirement that

⁵ The Medmarc Policy is unclear about whether the triggering date is the date of the advisory memorandum or the date the first claim is made against St. Jude. Compare *Ladner Ex. 1*, at 309 (date of advisory memorandum) with *id.* at 323 (date first claim made). The court need not resolve the issue, however, because both events happened during the Policy Period, as discussed below.

a bodily injury actually occur during the Policy Period, that St. Jude's advisory memorandum failed to identify a defect, that St. Jude has not presented evidence of a claim made against it during the Policy Period and that only claims from explants caused by paravalvular leakage could be aggregated. The court addresses each argument in turn.

A. Bodily Injury

AIC first argues that the bodily injury forming the basis of a claim must actually occur during the Policy Period.⁶ Section 1(b)(2) of the Medmarc Policy states that the policy only applies if "the bodily injury did not occur [after January 31, 2000]." Ladner Aff. Ex. 1, at 300. The Batch Clause amends the definition of the term "occurrence" and states that "[a]ll claims made ... seeking damages because of 'bodily injury' arising out of one batch will be deemed to have been made at the time the first of those claims is made against [St. Jude]." Id. at 323. AIC argues that the Medmarc Policy does not include a special definition of "occur" and therefore, the Batch Clause has no effect on section 1(b)(2).

⁶ AIC also asserts that the language of the AIC Policy is inconsistent with the Medmarc Policy, and therefore the AIC Policy does not follow form as to bodily injury. The AIC Policy states, "if the coverage provided by [Medmarc] applies on the basis of injury or damage which occurs during the period of that policy, then [AIC's] coverage only applies on the same basis and in a like manner to injury which occurs during [AIC's policy period]." Jones Aff. Ex. 50, at 2442. This language, however, is not inconsistent with the Medmarc Policy, and the court will not read an implied invalidation of the Batch Clause into the AIC Policy.

As a result, according to AIC, section 1(b)(2) imposes a requirement that the bodily injury actually occur during the Policy Period. The plain language of the policy does not support AIC's interpretation. First, the Medmarc Policy states that "with respect to 'bodily injury' ... the date of 'occurrence' is deemed to be ... the date of the advisory memorandum." Id. Ex. 1, at 309. Moreover, the interpretation advanced by AIC renders the Batch Clause meaningless by placing a claim in one policy period while assigning the bodily injury to another. If the Batch Clause changes the date that a "bodily injury" occurs under the policy, however, then section 1(b) and the Batch Clause are in harmony. Moreover, the bodily-injury provision limits liability, and the court must construe limitations against the insurer. Therefore, AIC's argument fails.⁷

B. Defects

AIC next argues that the Batch Clause does not apply because the January 21, 2000, notification and background memorandum do not identify a "known or suspected defect or deficiency." Specifically, AIC argues that the statement, "[b]ased on our internal investigation, we have concluded that the explants due to paravalvular leak in the AVERT Study are not related to the manufacturing of the valve or the manufacturing of the Silzone

⁷ The court did not consider the affidavit of Jon Lomasney, M.D., and therefore denies St. Jude's motion to strike his expert affidavit.

coated sewing cuff," by St. Jude invalidates any expression of a defect. Id. Ex. 28, at 2. St. Jude responds that the notification and background memorandum meet the policy requirements as an advisory memorandum. St. Jude is correct. The language of the notification and memorandum indicate that St. Jude had identified a defect: its Silzone-coated products were associated with "a statistically significant higher rate of paravalvular leak leading to valve explants." Id. Ex. 27, at 72703.

St. Jude's statement that the defect was not caused by a manufacturing defect does not invalidate the memorandum. Once a manufacturer has evidence of a defect or deficiency in its products, it need not wait to establish causality before acting to protect consumers. Here, St. Jude received evidence about its Silzone-coated products, notified physicians and recalled those products. Therefore, the January 21, 2000, notification and background memorandum identify a batch of products that share a defect, and accordingly the court finds that they are an advisory memorandum as defined by the Medmarc Policy.

C. Triggering Claim

AIC next argues that no claim was made during the Policy Period. A claim is made under the Medmarc Policy when "notice [of a person seeking damages] is received and recorded by any insurer" Id. Ex. 1, at 300. St. Jude attached a phone log to its January 28, 2000, letter to Medmarc showing that a patient had

contacted St. Jude about expenses and compensation related to his Silzone-coated valve. See Jones Aff. Ex. 38. Medmarc accepted the log as notice of a claim under the Batch Clause. See Larder Aff. Ex. 37, at 21600.

AIC asserts that St. Jude never demonstrated that a claim was made and received by an insurer during the Policy Period because the phone log provided to Medmarc is inadmissible hearsay. St. Jude responds that the phone log is not hearsay under Federal Rule of Evidence 801© because it is not being offered for the truth of the assertions, and even if it were, it falls under the business-record exception of Federal Rule of Evidence 803(6). St. Jude is correct. Therefore, AIC's argument that St. Jude did not notify an insurer of a claim within the Policy Period fails, and the court determines that a claim was made and received by an insurer during the Policy Period.

D. Scope of the Batch

Lastly, AIC argues that only claims for "paravalvular leakage leading to explant" are covered.⁸ The Batch Clause defines a batch

⁸ AIC cites decisions of the Illinois and Indiana courts in an action that proceeded in both jurisdictions. In those matters, district courts considering a similar batch clause arrived at opposite conclusions. Compare Allianz Ins. Co. v. Guidant Corp., 900 N.E.2d 1218, 1235-38 (Ill. App. Ct. 2008) (approving, in dicta, district-court conclusion that batch clause applies only to claims that arise out of same defect or deficiency) with Allianz Ins. Co. v. Guidant Corp., 884 N.E.2d 405, 412-13 (Ind. Ct. App. 2008) (noting, in dicta, district-court conclusion that batch clause applies to all products, regardless of whether claims allege same (continued...))

as "all products which have the same known or suspected defect which is identified in the same advisory memorandum." Id. Ex. 1, at 323. The Batch Clause applies to "all claims ... arising out of one batch." Id.

AIC argues that because the definition of batch uses the defect to identify the range of products included, only the particular defect is covered. St. Jude responds that the Batch Clause applies to all Silzone-coated products. The Batch Clause defines a batch in terms of *products* that share a defect. AIC's interpretation asks the court to rewrite the Batch Clause to focus exclusively on *defects*. The plain language, however, does not support AIC's interpretation. Under the plain language of the Batch Clause, once the batch of products is identified, the inquiry is solely whether the claim involves a product in the batch. Further, even if the court found the Batch Clause ambiguous, under Minnesota law it would have to choose the interpretation that favored coverage. Therefore, AIC's argument fails. The court has already determined that all Silzone-coated products shared a defect, and accordingly, the Batch Clause applies to claims for Silzone-coated products and places those claims and bodily injuries into the Policy Period.

⁸(...continued)
defect or deficiency). Both states' appellate courts determined, however, that the manufacturer had not issued an advisory memorandum. Therefore, the decisions offer little guidance or persuasive value in the instant dispute.

II. Exhaustion

AIC also argues that St. Jude is not entitled to partial summary judgment because it has not proven proper exhaustion of the underlying insurance. To establish a prima facie showing of coverage by an excess insurer, the insured must demonstrate exhaustion of underlying coverage. See Waste Mgmt. of Minn. v. Transcon, Ins. Co., 502 F.3d 769, 773-74 (8th Cir. 2007); 17A Lee R. Russ & Thomas F. Segalla, Couch on Insurance § 254:39 (3d ed. 1995 & Supp. 2001). Under Minnesota law, the terms of the insurance contract define the factors required to establish exhaustion. See Waste Mgmt., 502 F.3d at 773-74 (applying policy language basing liability on "final adjudication on the merits" to exhaustion); Royal Indem. Co. v. C.H. Robinson Worldwide, Inc., No. A08-0996, 2009 WL 2149637, at *3 (Minn. Ct. App. July 21, 2009) (considering exhaustion under terms of policy where policy defined loss and based exhaustion on payments for loss).

AIC argues that St. Jude must prove the proper exhaustion of all underlying claims. St. Jude responds that the policy language does not require an inquiry into the propriety of each underlying claim. St. Jude is correct. The AIC Policy states that AIC's duty to indemnify attaches to St. Jude's ultimate net loss "only after all Underlying Insurance has been exhausted by payments of the limits of such insurance." Id. Unlike the policy in Royal Indemnity, nothing in the AIC Policy ties exhaustion to the payment

of defined loss. Cf. Royal Indem., 2009 WL 2149637, at *3 (quoting policy language referring to loss). Therefore, the AIC Policy requires St. Jude to make a prima facie showing that the underlying insurers paid sums equal to the limits of their respective policies. The court is not aware of a dispute between the parties about whether each underlying insurer actually paid sums equal to its limit of liability. Accordingly, partial summary judgment is warranted, and the court finds that AIC is liable to St. Jude for payment of claims arising from Silzone-coated products that were settled or litigated in AIC's layer.

CONCLUSION

Based on the above, **IT IS HEREBY ORDERED** that:

1. The motion to strike the expert affidavit of Jon Lomasney, M.D. [Doc. No. 288] is denied as moot; and
2. The motion for partial summary judgment [Doc. No. 152] is granted.

Dated: September 20, 2010

s/David S. Doty
David S. Doty, Judge
United States District Court